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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,227	09/23/2002	Allan J Clarke	P32374	9571

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,227

Applicant(s)

CLARKE ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-52,54-58,60-69,71 and 72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-52,54-58,60-69,71 and 72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/11/05 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-52, 54-58, 60-69, 71 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is rejected in the use of the Markush language in lines 2-3. The phrase "each sub-unit being selected from: a linker, a closure cap, a drug substance-containing capsule compartment..., and a solid matrix" permits the selection of any of the four disclosed constituents as a sub-unit. For example, it the sub-unit can be at least two linker, or at least two solid matrix. However, lines 8-9 of claim 38, requires that the dosage form comprises at least two drug substance-containing sub-units. Does the dosage form comprise a linker, a closure cap, or a solid matrix? Accordingly, until

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further clarification, for examining purpose, the claim is interpreted as the multi-component dosage form comprises two drug substance-containing sub-units.

Claim 67 is rejected in the use of the phrase “wherein the drug substance in at least of the dosage forms”. The phrase appears incomplete.

Claim 67 is rejected in the use of the phrase “prior to administration to a patient, the sub-units of each dosage form are welded together”. Is this possible? The claim requires one of the subunit in one dosage form is a drug substance-containing capsule compartment, and the subunit for the other dosage form is a solid matrix. Is it intended to weld together the solid matrix to the drug substance-containing capsule compartment? For examining purpose, the claim is interpreted as the dosage form comprising multi-subunit joined together by a well, and at least one of the sub-unit contains a solid matrix. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38, 39, 51, 52, 54-56 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Glassman US 3,186,910.

Glassman discloses a capsule comprising two or more capsular bodies joined together and secured by a binder using heat to promote the bonding (column 1, lines

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12-37; column 5, lines 46-54; and fig. 15). The capsular bodies or compartment can be filled with desired medicament that can be the same or different from one another (column 5, lines 20-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-52, 54-58, 60-69, 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodhart et al. US 5,074,426, in view of Wong et al. US 5,236,689.

Goodhart discloses a multi-units capsule dosage comprising first and second capsule units (column 3, lines 17-19). Column 4, lines 1-31 disclose the process of preparing the capsule units comprising filling the two capsule units with medicinal preparation, applying adhesive paste on top of the medicinal preparation, turning the capsule units inwardly towards each other with the adhesive paste abutting each other, and adhesive paste would be applied to secure the capsule units together (Fig. 7). The multi-capsule units can be connected by separately molded section which is sealed to the capsule units by solvent welding (column 4, lines 28-31, Fig 3). Goodhart also teach there is an intermediated molded locking part used to secure the two capsule units together (column 4, lines 44-66). Furthermore, the capsule units are made with a

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female member (68) and male member (70) to provide a tight friction fit (Figs. 13&14, column 5, lines 5-16). Goodhart also teach the capsule units are detachable joined by adhesive, banding, or locking mechanical means (see abstract).

Goodhart does not teach combination of different active agent.

Wong teaches a multi-unit delivery system comprising a plurality of drug-containing units that comprises different drugs (see abstract; column 3, lines 50-54; and column 5, lines 55-57). Wong also teaches the drug units are in the form of a solid core or solid matrix, and the plurality of the drug units are aligned within the housings, wherein the housings are joined together by solvent weld, spin weld, thermal weld, ultrasonic weld, or similar welding operations (column 5, lines 30-40; and column 15, lines 9-25). Wong further teaches the housing member comprises an exit port (column 5, lines 41-49). Thus, it would have been obvious to one of ordinary skill in the art to modify the multi-unit capsule of Goodhart using the multi-capsule formulation for combination of drugs in view of the teaching of Wong, because Goodhart teaches capsule comprises two or more units desirable for varying dosages, because Goodhart teaches Goodhart teaches a multi-unit capsule suitable to separate drugs which are interactive, because Wong teaches a capsule dosage form capable of suitable for a variety of drug delivery profiles including simultaneous continuous delivery of several drugs or drug formulations.

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Claims 38, 39, 43, 44, 51, 52, 54-56, 58 and 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham US 5,085,033, in view of Wong et al. US 5,236,689.

Graham teaches a capsule formulation comprising active agent in matrix material (see abstract, column 3, lines 9-25). The active agent and matrix materials are filled in capsule halves, the capsule halves are sealed by the application of electromagnetic radiation whereupon the capsule halves are welded to each other (column 4, lines 19-29). Column 8 and examples 1-14 disclose the process for filling the capsule.

Graham does not teach combination of different active agent.

Wong teaches a multi-unit delivery system comprising a plurality of drug-containing units that comprises different drugs (see abstract; column 3, lines 50-54; and column 5, lines 55-57). Wong also teaches the drug units are in the form of a solid core or solid matrix, and the plurality of the drug units are aligned within the housings, wherein the housings are joined together by solvent weld, spin weld, thermal weld, ultrasonic weld, or similar welding operations (column 5, lines 30-40; and column 15, lines 9-25). Wong further teaches the housing member comprises an exit port (column 5, lines 41-49). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule formulation of Graham using the multi-capsule formulation for combination of drugs in view of the teaching of Wong, because Graham teaches a capsule suitable for medicament which is capable of using conventional capsule technology, because Graham teaches a capsule comprises matrix materials to achieve variations in the time of release of the active ingredient, because Wong teaches a

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capsule dosage form capable of suitable for a variety of drug delivery profiles including simultaneous continuous delivery of several drugs or drug formulations.

Response to Arguments

The indicated allowability of claim 70 is withdrawn in view of the newly discovered references to Wong et al., and Glassman. Rejections based on the newly cited references are disclosed above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal stroke extending to the right.

S. Tran
Examiner
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